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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,242	07/15/2003	Ricky Ulrich	003/267/SAP	8917

7590 03/13/2007

ATTN: MCMR-JA (Ms. Elizabeth Arwine- PATENT ATTY)
U. S. Army Medical Research and Materiel Command
504 Scott Street
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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,242	ULRICH ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *1-48,55-58 and 61-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-54,59,60 and 64-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed December 20, 2006 has been received and entered. Claims 1-67 remain pending in the instant application, of which claims 1-48, 55, 57, and 61-63 have been withdrawn from further consideration as being drawn to a non-elected invention.

Furthermore, Applicants have amended claim 56 to depend on claim 55, drawn to a non-elected B. pseudomallei vaccine. Accordingly, claims 56 and 58 now belong with non-elected Group XVI, as set forth in the restriction requirement mailed March 16, 2006.

Accordingly, claims 1-67 are pending in the instant application, of which claims 1-48, 55-58, and 61-63 have been withdrawn from further consideration as being drawn to a non-elected invention.

This application contains claims 1-48, 55-58 and 61-63 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

1. The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of Applicants amendment.

Claim Objections

2. The objection of claims 53-54 and 58-60 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

3. The rejection of claims 64-67 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

It is noted that Applicants have requested that this rejection be held in abeyance until the claims are allowed. However, until the deposit is perfected, this rejection is maintained for reasons of record.

The specification lacks complete deposit information for the deposit of GB8:bpml3, it is not clear that host cells possessing the identical properties of GB8:bpml3 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a host cell is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed cell, this method will not necessarily reproduce host cells which are chemically and structurally identical to those claimed. Undue experimentation would be required to screen all of the possible species to obtain the claimed host cells.

Because one skilled in the art could not be assured of the ability to practice the

invention as claimed in the absence of the availability of the GB8:bpml3 host cells a suitable deposit for patent purposes, evidence of public availability of the GB8:bpml3 host cells or evidence of the reproducibility without undue experimentation is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

4. The rejection of claims 56 and 58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 49-54, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by DeShazer et al is maintained.

Applicants are asserting that DeShazer et al do not mention Bmal3, nor a method of making a B. mallei strain with a mutation in Bmal3.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that DeShazer et al do not mention Bmal3, nor a method of making a B. mallei strain with a mutation in Bmal3. However, Applicants will note that the claims simply do not set forth a structural requirement for the recited Bmal3 molecule, (e.g., SEQ ID NO:). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Applicants specification (pages 14-15) defines nucleic acid molecules of the invention to "comprise a sequence substantially different from those described but which due to the degeneracy of the genetic code, still encode the protein **or fragments thereof.**" (Emphasis added). The encoded protein disclosed by DeShazer et al shares "fragments" with the Bmal3 molecule of the instant invention. Accordingly, each and every limitation has been addressed by the disclosure of DeShazer et al.

The claims are directed to a mutant B. mallei strain with reduced virulence wherein said strain is altered in expression or function of Bmal3.

DeShazer et al (Microbial Pathogenesis (Vol. 30, pp 253-269, May 2001) disclose of B. mallei strains with reduced virulence having disrupted yggB, yafJ, manC, wcbB, wcbF, wcbL, wcbM, wcbP, wcbQ, and wcbR genes. (See abstract, Figure 2 and Materials and Methods section).

It is noted that Applicants specification specifically sets forth that nucleic acid molecules of the invention "comprise a sequence substantially different from those described, but which due to the degeneracy of the genetic code, still encode the protein **or fragments thereof.**" (Specification pages 14 & 15).

In view that DeShazer et al disclose of B. mallei strains with reduced virulence having disrupted genes, which genes inherently share "fragments" (which can be as small as a single codon) in common with the Bmal3 gene referenced in the claims, the disclosure of DeShazer et al is deemed to anticipate the claimed invention.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Navarro
Primary Examiner
March 5, 2007